



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IX

75 Hawthorne Street

San Francisco, CA 94105-3901

Dow R. Wilson
President and Chief Executive Officer
Varian Medical Systems
3100 Hansen Way
Palo Alto, California 94304

Dear Mr. Wilson:

Region IX of the United States Environmental Protection Agency ("EPA") is issuing this letter to determine the Clean Air Act ("CAA" or "Act") compliance status of Varian Medical Systems ("VMS") with respect to the Mandatory Greenhouse Gas Reporting Rule at 40 C.F.R. Part 98¹ (hereafter "the GHG² Reporting Rule") and with the portion of the GHG Reporting Rule that addresses reporting by *suppliers of industrial greenhouse gases* at 40 C.F.R. Part 98, Subpart OO, 40 C.F.R. §§ 98.410-418. Pursuant to Section 114 of the Act, 42 U.S.C. § 7414, VMS is hereby required to provide the following information requested in this letter. In responding to this request, VMS shall use the instructions provided in Enclosure 1.

1. For each calendar year from 2010 through 2014, please state whether VMS *produced fluorinated GHGs* or nitrous oxide (" N_2O ") at its Palo Alto facility.
2. Please state whether VMS has been a *bulk importer of fluorinated GHGs* or N_2O at any time from January 1, 2010 to the present. If yes, for each calendar year from 2010 through 2014, please state whether VMS' combined annual *bulk imports* of N_2O , *fluorinated GHGs*, and CO_2 equaled or exceeded 25,000 metric tons of *carbon dioxide equivalent* (" CO_2e ") and provide the basis for that conclusion, such as supporting calculations and documentation.
3. Please state whether VMS has been a *bulk exporter of fluorinated GHGs* or N_2O at any time from January 1, 2010 to the present. If yes, for each calendar year from 2010 through 2014, please state whether VMS' combined annual *bulk exports* of N_2O , *fluorinated GHG*, and CO_2 equaled or exceeded 25,000 metric tons of CO_2e and provide the basis for that conclusion, such as supporting calculations and documentation.
4. For each calendar year from 2010 through 2014 in which VMS (i) *produced fluorinated GHGs* or N_2O , or (ii) *imported or exported industrial GHG* with annual *bulk imports or exports* of N_2O , *fluorinated GHGs*, and CO_2 that in combination are equivalent to 25,000 metric tons of CO_2e or

¹ The following is the link to the GHG Reporting Rule:

http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title40/40cfr98_main_02.tpl.

² All terms in italics are defined at 40 C.F.R. § 98.6 or 40 C.F.R. § 98.410.

more, please state whether VMS or its designated representative³ submitted an annual report, as required by 40 C.F.R. § 98.416, using EPA's electronic GHG Reporting Tool ("e-GGRT")⁴ and provide the facility name and greenhouse gas reporting program ("GHGRP") identification number as entered into e-GGRT.

5. If VMS or its designated representative has not submitted annual reports, as required by 40 C.F.R. § 98.416, please report the *GHG* emissions that would result from the release of each *fluorinated GHG* or *N₂O produced, imported, exported, transformed, or destroyed* during each calendar year from 2010 through 2014, in accordance with 40 C.F.R. Part 98, Subpart OO, and submit them through e-GGRT.

VMS shall submit its response to this request postmarked no later than thirty (30) calendar days after receipt of this letter. All information submitted in response to this request must be certified in a signed, separate statement as true, correct, accurate, and complete, to the best of his/her knowledge, by an individual with sufficient knowledge and authority to make such representations on behalf of VMS (see Enclosure 2).

If VMS seeks to withhold any document(s) based on a claim of attorney-client communications privilege or the attorney work product doctrine in its response to this information request, VMS shall provide with its response a privilege log for each document containing the following information: (i) the date, author(s), every individual to whom the document was originally sent, every individual who subsequently acquired the document, the purpose for which the document was sent to or obtained by those individuals, and the employment titles of the authors and recipients; (ii) the subject matter of the document; (iii) the privilege claimed for the document and all facts supporting the claim of privilege; (iv) the primary purpose(s), including the business purposes, for which the document was made; (v) the question(s) in this information request to which the document is responsive to; and (vi) all facts contained in the document that are responsive to a question in this information request.

The responsive information shall be accompanied by a cover letter sent via certified mail with return receipt requested to the following address:

Ms. Kathleen H. Johnson
Director, Enforcement Division
U.S. Environmental Protection Agency
75 Hawthorne Street
San Francisco, CA 94105

Attn: Andrew Chew (ENF-2-1)

Please be advised that under Section 113(a) of the Act, 42 U.S.C. § 7413(a), failure to provide the information and documents required by this letter may result in an order requiring compliance, an order assessing an administrative penalty, or a civil action for appropriate relief. Section 113(b) of the Act, 42 U.S.C. § 7413(b), provides for the assessment of a civil penalty, which has been adjusted for inflation to \$37,500 per day, for each violation of the Act. See 40 C.F.R. § 19.4 (for penalties effective after January 12, 2009). In addition, Section 113(c) of the Act, 42 U.S.C. § 7413(c), provides criminal

³ See 40 C.F.R. § 98.4 for the authorization and responsibilities of the designated representative.

⁴ See <http://www.epa.gov/ghgreporting/reporters/datasystem/index.html> for information on e-GGRT.

penalties for knowingly making any false material statement in, or omitting material information from, any report required under the Act. The information provided by VMS may be used by the United States in administrative, civil, or criminal proceedings.

You may, if you desire, assert a confidential business information ("CBI") claim on behalf of VMS covering part or all of the information provided to EPA in response to this letter. Any such CBI claim must conform to the requirements set forth in 40 C.F.R. Part 2, particularly 40 C.F.R. § 2.203. You are advised that certain information may be made available to the public pursuant to Section 114(c) of the Act, 42 U.S.C. § 7414(c), and 40 C.F.R. § 2.301, notwithstanding a claim that such information is entitled to confidential treatment. Please note that emission data provided pursuant to Section 114 of the Act, 42 U.S.C. § 7414, is not entitled to confidential treatment under 40 C.F.R. Part 2, Subpart B. Emission data is defined at 40 C.F.R. § 2.301(a)(2). If no claim of confidentiality is received with your reply, the information may be made available to the public without notice to VMS.

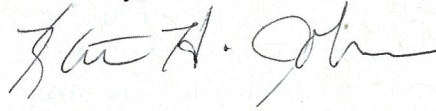
This information request is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act because it is not the "collection of information" within the meaning of 44 U.S.C. §§ 3502(3) and 3518(c)(1), since it is being directed to fewer than ten persons or entities and is being issued during the conduct of an investigation involving the EPA against specific individuals or entities. See also 5 C.F.R. §§ 1320.3(c) and 1320.4.

We would also like to take this opportunity to advise you that VMS may qualify as a "small business" under the Small Business Regulatory Enforcement and Fairness Act ("SBREFA"). Please review the enclosed SBREFA Information Sheet, which is designed to provide information on compliance assistance to entities that may qualify as small businesses as well as to inform them of their right to comment to the SBREFA Ombudsman concerning EPA's enforcement activities. Please be aware that SBREFA does not eliminate VMS' responsibility to respond in a timely fashion to any complaint or information request that EPA may issue or other enforcement action that EPA may take, nor does SBREFA create any new rights or defenses under the law other than the right to comment to the SBREFA Ombudsman.

If VMS anticipates that it will not be able to respond fully to this request within the time period specified, VMS must submit a sworn declaration by a responsible corporate/government official within ten (10) calendar days after receipt of this letter specifying what information will be provided by the allotted deadline, describing the efforts that have been/are being undertaken to obtain the remaining other responsive information, and providing a detailed schedule of when such other responsive information will be provided. Upon receipt and based upon such declaration, EPA may extend the time in which to respond to this information request. Also, please contact EPA if VMS determines that a full response to a particular request for information would require the submission of an extremely large number of documents. Based upon such notification, EPA may modify the scope of the documents required to be produced.

If you have any questions regarding this request, please contact Andrew Chew of my staff at (415) 947-4197 or your attorney can contact Daniel Reich, Office of Regional Counsel, at (415) 972-3911. Thank you for your cooperation in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathleen H. Johnson", written in a cursive style.

Kathleen H. Johnson
Director, Enforcement Division

Enclosures

cc: Wayne Kino, Bay Area AQMD
James Ryden, California Air Resources Board

ENCLOSURE 1: Instructions

1. All responsive documents must be:
 - a. provided as an accurate and legible copy in a searchable PDF file format;
 - b. submitted on a disk (CD or DVD media);
 - c. number stamped in sequential order (BATES stamped); and
 - d. submitted as an attachment to a letter postmarked no later than 30 calendar days after receipt of this letter.
2. Prepare a cover letter that includes a written response to all requests referencing the request number to which each answer or document pertains. In addition, attach to the cover letter the signed certification by a corporate/government official with authority to make such representations for VMS, described in the body of the above information request letter.
3. To the extent that VMS has no responsive information or documents for any particular request, this must be explicitly stated in the response.
4. Where documents or information necessary for a response are neither in your possession nor available to you, indicate in your response why such documents or information is not available or in your possession and identify any source that either possesses or is likely to possess such information.
5. To the extent that a document is responsive to more than one request, this must be so indicated and only one copy of the document need be provided.

ENCLOSURE 2: CERTIFICATION

[This Certification is for signature by the president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or another executive with authority to perform similar policy or decision-making functions of the corporation.]

Varian Medical Systems is submitting the enclosed documents in response to the U.S. Environmental Protection Agency's ("EPA") request for information, issued pursuant to Section 114(a) of the Clean Air Act, to determine whether the facility is in compliance with the Clean Air Act, specifically the Greenhouse Gas Reporting Rule at 40 C.F.R. Part 98, Subpart OO.

I certify that I am fully authorized by Varian Medical Systems to provide the above information on its behalf to EPA.

I certify under penalty of law that I have personally examined and am familiar with the statements and information submitted in the enclosed documents, including all attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true, correct, accurate and complete. I am aware that there are significant penalties for submitting false statements and information, or omitting required statements and information, including the possibility of fines and imprisonment for knowing violations.

Date: _____

Name (Printed): _____

Signature: _____

Title: _____

Toxic Substances Control Act (TSCA) Hotline
tsca-hotline@epa.gov or 1-202-554-1404

Wetlands Information Helpline
www.epa.gov/owow/wetlands/wetline.html or 1-800-832-7828

State and Tribal Web-Based Resources

State Resource Locators
www.envcap.org/statetools

The Locators provide state-specific contacts, regulations and resources covering the major environmental laws.

State Small Business Environmental Assistance Programs (SBEAPs)
www.smallbiz-enviroweb.org

State SBEAPs help small businesses and assistance providers understand environmental requirements and sustainable business practices through workshops, trainings and site visits. The website is a central point for sharing resources between EPA and states.

EPA's Tribal Compliance Assistance Center
www.epa.gov/tribalcompliance/index.html

The Center provides material to Tribes on environmental stewardship and regulations that might apply to tribal government operations.

EPA's Tribal Portal
www.epa.gov/tribalportal/

The Portal helps users locate tribal-related information within EPA and other federal agencies.

EPA Compliance Incentives

EPA provides incentives for environmental compliance. By participating in compliance assistance programs or voluntarily disclosing and promptly correcting violations before an enforcement action has been initiated, businesses may be eligible for penalty waivers or reductions. EPA has two such policies that may apply to small businesses:

EPA's Small Business Compliance Policy
www.epa.gov/compliance/incentives/smallbusiness/index.html

This Policy offers small businesses special incentives to come into compliance voluntarily.

EPA's Audit Policy
www.epa.gov/compliance/incentives/auditing/auditpolicy.html

The Policy provides incentives to all businesses that voluntarily discover, promptly disclose and expeditiously correct their noncompliance.

Commenting on Federal Enforcement Actions and Compliance Activities

The Small Business Regulatory Enforcement Fairness Act (SBREFA) established a SBREFA Ombudsman and 10 Regional Fairness Boards to receive comments from small businesses about federal agency enforcement actions. If you believe that you fall within the Small Business Administration's definition of a small business (based on your North American Industry Classification System designation, number of employees or annual receipts, as defined at 13 C.F.R. 121.201; in most cases, this means a business with 500 or fewer employees), and wish to comment on federal enforcement and compliance activities, call the SBREFA Ombudsman's toll-free number at 1-888-REG-FAIR (1-888-734-3247), or go to their website at www.sba.gov/ombudsman.

Every small business that is the subject of an enforcement or compliance action is entitled to comment on the Agency's actions without fear of retaliation. EPA employees are prohibited from using enforcement or any other means of retaliation against any member of the regulated community in response to comments made under SBREFA.

Your Duty to Comply

If you receive compliance assistance or submit a comment to the SBREFA Ombudsman or Regional Fairness Boards, you still have the duty to comply with the law, including providing timely responses to EPA information requests, administrative or civil complaints, other enforcement actions or communications. The assistance information and comment processes do not give you any new rights or defenses in any enforcement action. These processes also do not affect EPA's obligation to protect public health or the environment under any of the environmental statutes it enforces, including the right to take emergency remedial or emergency response actions when appropriate. Those decisions will be based on the facts in each situation. The SBREFA Ombudsman and Fairness Boards do not participate in resolving EPA's enforcement actions. Also, remember that to preserve your rights, you need to comply with all rules governing the enforcement process.

EPA is disseminating this information to you without making a determination that your business or organization is a small business as defined by Section 222 of the Small Business Regulatory Enforcement Fairness Act or related provisions.

U.S. EPA Small Business Resources Information Sheet

The United States Environmental Protection Agency provides an array of resources, including workshops, training sessions, hotlines, websites and guides, to help small businesses understand and comply with federal and state environmental laws. In addition to helping small businesses understand their environmental obligations and improve compliance, these resources will also help such businesses find cost-effective ways to comply through pollution prevention techniques and innovative technologies.

EPA's Small Business Websites

Small Business Environmental Homepage - www.smallbiz-enviroweb.org

Small Business Gateway - www.epa.gov/smallbusiness

EPA's Small Business Ombudsman - www.epa.gov/sbo or 1-800-368-5888

EPA's Compliance Assistance Homepage

[www.epa.gov/compliance/assistance/
business.html](http://www.epa.gov/compliance/assistance/business.html)

This page is a gateway to industry and statute-specific environmental resources, from extensive web-based information to hotlines and compliance assistance specialists.

EPA's Compliance Assistance Centers

www.assistancecenters.net

EPA's Compliance Assistance Centers provide information targeted to industries with many small businesses. They were developed in partnership with industry, universities and other federal and state agencies.

Agriculture

www.epa.gov/agriculture/

Automotive Recycling

www.ecarcenter.org

Automotive Service and Repair

www.ccar-greenlink.org or 1-888-GRN-LINK

Chemical Manufacturing

www.chemalliance.org

Construction

www.cicacenter.org or 1-734-995-4911

Education

www.campuserc.org

Food Processing

www.fpeac.org

Healthcare

www.hercenter.org

Local Government

www.lgean.org

Metal Finishing

www.nmfrf.org

Paints and Coatings

www.paintcenter.org

Printed Wiring Board Manufacturing

www.pwbrf.org

Printing

www.pneac.org

Ports

www.portcompliance.org

U.S. Border Compliance and Import/Export Issues

www.bordercenter.org

Hotlines, Helplines and Clearinghouses

www.epa.gov/epahome/hotline.htm

EPA sponsors many free hotlines and clearinghouses that provide convenient assistance regarding environmental requirements. Some examples are:

Antimicrobial Information Hotline

info-antimicrobial@epa.gov or
1-703-308-6411

Clean Air Technology Center (CATC) Info-line

www.epa.gov/ttn/catc or 1-919-541-0800

Emergency Planning and Community Right-To-Know Act

[www.epa.gov/superfund/resources/
infocenter/epcra.htm](http://www.epa.gov/superfund/resources/infocenter/epcra.htm) or 1-800-424-9346

EPA Imported Vehicles and Engines Public Helpline

www.epa.gov/otaq/imports or
734-214-4100

National Pesticide Information Center

www.npic.orst.edu/ or 1-800-858-7378

National Response Center Hotline -

to report oil and hazardous substance spills
www.nrc.uscg.mil or 1-800-424-8802

Pollution Prevention Information Clearinghouse (PPIC)

www.epa.gov/opptintr/ppic or
1-202-566-0799

Safe Drinking Water Hotline

[www.epa.gov/safewater/hotline/index.
html](http://www.epa.gov/safewater/hotline/index.html) or 1-800-426-4791

Stratospheric Ozone Protection Hotline

www.epa.gov/ozone or 1-800-296-1996